one capture binding moiety **308***a* and **308***b* (e.g., an antibody, a nucleic acid, or the like) that can specifically interact with and capture the analyte of interest for detection. The characteristics of the standard solution sachet **318** can be used to test for quantitative delivery of the calibration standard onto the calibration strip **306***b* and to test the response of the capture binding moiety **308***b* to the analyte of interest. In one embodiment, the sample pad **312** may include flow indicator lines **310***a* and **310***b* (e.g., a water soluble dye) that indicate whether or not sample has successfully diffused through the test strip **301***a* and the calibration strip **301***b*.

[0047] In one embodiment, the sample pad **216***a*, **216***b*, or **316** may be configured to absorb and dispense a predetermined amount of a fluid from the fluid that is applied thereto. That is, the sample pad **216***a*, **216***b*, or **316** may be fabricated from an absorbent-type material that may saturated with fluid and then when, for example, the sample pad **216***a*, **216***b*, or **316** is compresses or squeezed, the sample pad **216***a*, **216***b*, or **316** can dispense a predetermined amount of a fluid therefrom. In one embodiment, the sample pad **216***a*, **216***b*, or **316** may be made of cellulose, glass fiber or other material where the fluid sample is applied to the lateral flow device and, if necessary modifies it to improve the results of the assay. This might be by modifying pH, filtering out solid components, separating whole blood constituents, adsorbing out unwanted antibodies or some other test specific variable.

[0048] For some applications, the sample pad **216***a*, **216***b*, or **316** may be pretreated by dipping it into a specific buffer containing a mix of a solution comprised of soluble proteins, surfactants/detergents, and other polymers. These may allow for a steady flow and prevent nonspecific binding of sample components to the pad **216***a*, **216***b*, or **316**.

[0049] In some embodiments, the sample may be added to the sample pad **216***a*, **216***b*, or **316** by collecting a liquid sample (e.g., blood, urine, or saliva) and adding a selected volume of the sample to the sample pad. In other embodiment, the sample may be added to the sample pad **216***a*, **216***b*, or **316** by soaking the pad with a fluid sample. For example, the sample pad **216***a*, **216***b*, or **316** may be soaked with saliva by inserting the sample collection pad **216***a*, **216***b*, or **316** end of the device **200** or **300** into the mouth to collect a saliva sample.

[0050] In one embodiment, the conjugate pad **204***a*, **204***b*, **304***a*, **304***b* is made of a non-absorbent material such as fiberglass pad, polyester, rayon or a similar material. The conjugate pad **204***a*, **204***b*, **304***a*, **304***b* is typically fabricated from a synthetic material (at least when using a gold conjugate) to ensure the efficient release of its contents.

[0051] As its name implies, the assay's detection conjugate (e.g., colloidal gold) is dried down and held in place in the conjugate pad **204***a*, **204***b*, **304***a*, **304***b* until a liquid test sample is applied to the sample pad. The liquid from the sample, by capillary action moves into the conjugate pad **204***a*, **204***b*, **304***a*, **304***b*, re-hydrates the dry conjugate and allows the mixing of the sample with the conjugate. The complex of conjugate and analyte then moves into and up the assay strip **206***a*, **206***b*, **306***a*, **306***b*. Pretreatment of the conjugate pad **204***a*, **204***b*, **304***a*, **304***b* helps to ensure the conjugate releases at the proper rate and enhances its stability. The pretreatment is performed in the same way as with the sample pad **216***a*, **216***b*, or **316**.

[0052] In one embodiment, the at least one capture binding moiety **208***a*, **208***b*, **308***a*, **308***b* may be added to the test or calibration strips with a dispenser that gently slides a soft capillary tube across the membrane. A dispenser pump releases a constant volume of the reagents down the length of the membrane. This system is simple, easy to use, and low cost. They can be somewhat cumbersome in large scale manufacturing and many systems require a technician to constantly feed the nitrocellulose cards and to monitor reagent levels as well as the quality of the test and control lines.

[0053] An alternative method of applying the at least one capture binding moiety **208***a*, **208***b*, **308***a*, **308***b* includes a non-contact aerosol system. These sprayers dispense solutions in controlled ultrafine, ultra- small volume aerosols. These devices project very fine droplets of reagent onto the membrane and overlap the drops to create a continuous line. Spraying offers much more control of the reagent application, but it also adds capital expense and increases the complexity of strip manufacturing. These devices are more appropriate in very large scale manufacturing or when a reader with tight tolerances will be used to analyze the lateral flow test strips.

[0054] In the foregoing, addition of one line of the at least one capture binding moiety **208***a*, **208***b*, **308***a*, **308***b* onto each of the test or calibration strips is discussed. However, one will appreciate that a cassette **200** or **300** may include multiple test and control lines that may each be configured to interact with a different analyte of interest.

[0055] Referring now to FIGS. **4**A and **4**B, plan and side views of a diagnostic test system **240** are illustrated. In one embodiment, the diagnostic test system **240** may include a handheld device **250** and a testing apparatus **260**.

[0056] In the illustrated embodiment, the handheld device **250** is an iPhone. However, the handheld **250** device can be essentially any cell phone device, digital camera device, or a similar device that has an onboard camera/image capture function, data collection and analysis capabilities, data and results display capabilities, and, preferably, the ability to communicate with one or more remote computer or cellphone networks for data upload, querying a data analysis algorithm, querying a decision support algorithm, and the like. In the illustrated embodiment, the handheld device **250** includes a front-directed camera **280**, a back-directed camera (not shown) that is directed into the testing apparatus, a display screen **290**, and audio input and output ports **295***a* and **295***b*. The display screen **290** can be used for display of data and results. In addition, the display screen **290** may include touch-screen capabilities that can be used for input of data or commands. Additionally the front-directed camera can be used for imaging QR and bar code information identifying the test to be performed and providing lot number, expiration date, and control values as well as other parameters as needed for test identification, calibration, results interpretation, and data reporting.

[0057] In one embodiment, the testing apparatus **260** is designed to be securely coupled to the handheld device **250**. For example, the testing apparatus **260** may be designed to fit a specific class or brand of handheld devices. The testing apparatus includes a cassette port **270** that is designed to allow an assay device, such as a lateral flow immunoassay cassette **105** (see FIG. **1**), to be inserted into the testing apparatus **260**. Additionally, an interior portion of the testing apparatus **260** may be painted with a flat black color so as to avoid extraneous and reflected light. In addition, the testing apparatus **260** includes a number of internal components (e.g., i/o ports, power ports, light source(s), lens(es), light conducting media, etc.) that are designed to transform the handheld device **250** into a device that can be used to collect and